

REMARKS

No claims have been added, cancelled or amended. Claims 11, 12, 16, 21-25, 35, 36, 40, 47 and 50 were previously withdrawn from consideration. Claims 11, 12, 16 and 21-50 are pending in the present application. No new matter has been added to the application.

Independent Claim 26 and Dependent Claims 27-34, 37-39, 41-46, 48 and 49

Claims 26-34, 37-39, 41-46, 48 and 49 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Johnstone (WO 98/33487) in view of DeLong (WO 99/50241).

The Examiner argues that “Johnstone teaches the use of prostaglandins (preferably PGA, PGE, or PGF) [and] derivatives or analogues thereof, for the use in stimulating hair loss,” but “does not specifically teach the PGF analogues of the instant invention or treatment involving both a prostaglandin and a vasodilator.” Office action, pages 2-3. The Examiner further recites that DeLong teaches “PGF analogues for the treatment of bone disorders and glaucoma,” and exemplified “11-hydroxylamino-17-phenyl-17-trinor-PGF_{2α}, wherein W is CH₂, X is OH, Y is a single bond, p is 2, q is 0, Z is phenyl, R₁ is COOH, R₅ is H, R₆ is H, a is a double bond, and b is a single bond.” Office action, page 3. Therefore, the Examiner contends it would have been “obvious to one of ordinary skill in the art at the time of the invention to substitute the prostaglandins of Johnstone with a prostaglandin of DeLong because (1) Johnstone teaches that PGF and its derivatives and analogs are preferred for the treatment of hair loss; and (2) DeLong teaches a PGF analogue.” Applicant respectfully disagrees.

To establish a *prima facie* case of obviousness: 1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the teachings; 2) there must be a reasonable expectation of success; and 3) the references must teach or suggest all of the claimed limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art, and not based on Applicant’s disclosure. *In Vaeck*, 947 F. 2d 422, 20 USPQ2d 1438 (Fed. Cir. 1991).

Independent claim 26 and its dependent claims recite compositions comprising a specific class of prostaglandins, namely “oximyl- and hydroxylamino prostaglandins,” and methods of administering these compositions to treat hair loss. The claimed prostaglandins have either an oximyl- or an hydroxylamino group at the C11 position on the alicyclic ring.

Johnstone discloses compositions containing prostaglandins, derivatives or analogues thereof and their use for stimulating the growth of hair. Johnstone contemplates various classes of prostaglandins as depicted by the general structures on page 12, lines 1 to 15. Prostaglandins of Johnstone contain hydrogen, hydroxyl or oxo- group at C9, C10 and/or C11 positions on the alicyclic ring. Johnstone's preferred embodiments are prostaglandins having hydroxyl groups at C9 and C11 positions. Page 7, lines 17-19 and 23. Representative exemplary compounds are provided on pages 14-16. Johnstone further discloses that the derivatives or analogues that are useful in the practice of the invention disclosed therein "are derivatives of the prostaglandins characterized by presence or lack of modifications to their omega chain and the presence or lack of various modifications of the alpha chain." Page 12, lines 13-15.

First, Johnstone does not teach or suggest a derivative of prostaglandin containing an oximyl- or an hydroxylamino group at the C11 position on the alicyclic ring, as claimed in the present application.

Second, while Johnstone mentions methods of enhancing hair growth, Johnstone does not stand for the proposition that all prostaglandins, or even those useful in treating glaucoma, are useful for enhancing hair growth. To the contrary, Johnstone has provided activity data relating only to one exemplary compound, namely, "13,14-dihydro-17-phenyl-18,19,20-trinor-PGF₂ α isopropyl ester" (a.k.a. latanoprost) in support of the proposed use. This exemplary compound, however, is not one of the claimed oximyl or hydroxylamino prostaglandins. Referring to the state of the art, Johnstone merely states that prostaglandins of various types, including its exemplary compound, are useful in the treatment of glaucoma and proposed a new use for a particular class of prostaglandins and derivatives thereof (i.e. stimulation of hair growth). Pages 4 to 5. Johnstone, however, does not disclose that prostaglandins and their derivatives/anlogs as contemplated, if useful in treating glaucoma, necessarily stimulate the growth of hair. In fact, Johnstone teaches away from this notion. Particularly, Johnstone speculates that some of his proposed derivatives, "may be irritating or otherwise not optimal, and in certain cases not even useful due to adverse effects...." Page 18, lines 2 to 12. Johnstone does not provide any guidance that would enable one skilled in the art to readily ascertain which of Johnstone's numerous prostaglandin compounds would be useful in the treatment of mammalian hair conditions. Moreover, as discussed above, the claimed "oximyl- and hydroxylamino prostaglandins" of the present application are different from the prostaglandins of Johnstone.

DeLong discloses oximyl- and hydroxylamino prostaglandin analogs used in the treatment of glaucoma. DeLong does not teach or suggest that the prostaglandin analogs disclosed therein can also be useful in treating hair loss as described and claimed in the instant application. In fact, DeLong is completely silent with respect to hair loss.

The Applicant respectfully asserts that in the absence of any data or teachings in Johnstone, suggesting that all “oximyl- and hydroxylamino prostaglandins” useful in treating glaucoma are necessarily useful in treating hair loss, one skilled in the art would not be motivated to combine DeLong with Johnstone. Johnstone’s teaching away, namely, that some of Johnstone’s derivatives “may be irritating or otherwise not optimal, and in certain cases not even useful due to adverse effects...”, acts as a disincentive for combining DeLong and Johnstone, and does not provide any reasonable expectation of such a combination being successful. Page 18, lines 2 to 12.

In view of the foregoing, the Applicant respectfully asserts that a *prima facie* case of obviousness has not been established. Accordingly, withdrawal of the obviousness rejection is respectfully requested.

Consequently, the Applicant respectfully requests reconsideration and allowance of independent claim 26 and dependent claims 27-34, 37-39, 41-46 and 48-49. Should any issues remain that preclude the allowance of the application, the Examiner is strongly encouraged to contact the undersigned at the telephone number identified below.

Respectfully submitted,



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